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**CERTIFICATE OF MAILING BY "FIRST-CLASS MAIL"**


**Attorney Docket No. :** 208.3A2  
**Serial No. :** 09/675,323  
**Applicant(s) :** Henry Lardy, et al.  
**For :** Therapeutic Treatment of Androgen  
Driven Conditions  
**Attorney :** Daryl D. Muenchau, Reg. No. 36,616  
**Date of Deposit :** September 3, 2004

I hereby certify that the accompanying

Request for Continued Examination Transmittal (including extension request) (in duplicate); Amendment and Response to Office Action; Information Disclosure Statement (Form PTO-1449); and Return Postage Prepaid Postcard

are being deposited with the United States Postal Service "First-Class Mail" service on the date indicated above and are addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Candace Fuller  
Candace Fuller

	Application No.	Applicant(s)	
	09/675,323	LARDY ET AL.	
Examiner		Art Unit	
Elli Peselev		1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 40-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                                    |

Claims 40-55 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the Office Action of June 6, 2003.

Applicant's arguments filed December 8, 2003 have been considered but have not been found persuasive.

The prior art cited by applicant's has been considered but has not been found persuasive. The cited art is limited to prevention of prostate cancer with a limited number of compounds which are unrelated to the compounds encompassed by the instant claims. Note that each case is considered on its own merits. In the instant case there is no evidence that the claimed methods are effective in preventing any androgen responsive diseases. Further, note that it cannot be predicted on the basis of unrelated compounds in the prior art whether the claimed methods will be effective in preventing said diseases.

Also the instant claims encompass a large number of structurally unrelated compounds and it cannot be ascertained on the basis of data relating to 23 compounds whether the structurally unrelated compounds encompassed by the instant claims will similar activity. For example, compounds wherein R6, R7, R8, R12, R13, R14, R15, R16, R17, R18 and R19 are each hydrogen and a compound wherein each of the said R substituents is a peptide, heterocycle or a substituted oligosaccharide are structurally unrelated compounds and would not be expected to have the same activity, chemical or physical characteristics.

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Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The numbers set forth in claim 55 render the claim indefinite since it is not clear what is encompassed by the said numbers i.e. the scope of the invention cannot be determined.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

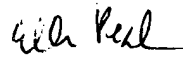
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 9.00-5.30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

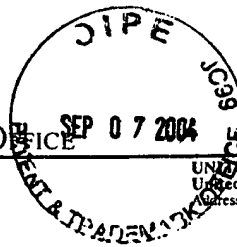
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev

  
ELLI PESELEV  
PRIMARY EXAMINER  
GROUP 1200



UNITED STATES PATENT AND TRADEMARK OFFICE



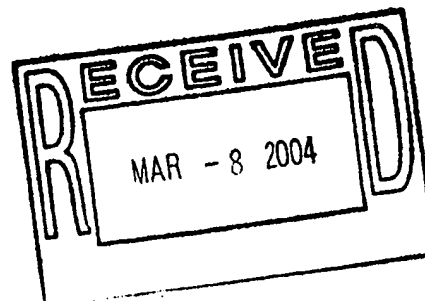
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/675,323	09/28/2000	Henry A. Lardy	HOLISED.063A	2363
26551	7590	03/05/2004	EXAMINER PESELEV, ELLI	
HOLLIS-EDEN PHARMACEUTICALS, INC. 4435 EASTGATE MALL SUITE 400 SAN DIEGO, CA 92121			ART UNIT 1623	PAPER NUMBER

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Hollis-Eden Pharmaceuticals, Inc.  
DOCKETED: *Mar 3/8/04*  
DUE DATE: *6/05/04*



*208.3 US*

PTO-90C (Rev. 10/03) *Reminded 5/05/04*  
*Reminded 4/05/04*